DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 4 - 2004

Hansung Econet Co. Ltd.
C/o Mr. Sanghun Kim
Econet USA, Inc.
11 Mill Creek
Irvine, California 92612

Re: K033116
Trade/Device Name: Opti-Rider Deluxe
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: February 25, 2004
Received: February 25, 2004

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of March 12, 2004 regarding the device named above. The letter was incorrectly addressed to Hansug Econet Co. Ltd. Hansung Econet Co. Ltd is the correct addressee.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

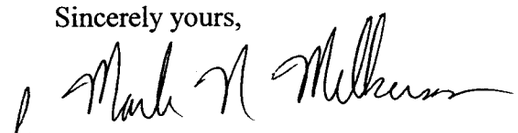
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033116/ A00

Indications for Use

510(k) Number (if known) : K033116

Device Name :

Proprietary Name : Opti-Rider Deluxe

Common/Usual Name : Scooter

Classification Name : Motorized three-wheeled vehicle

Indications For Use :

The Opti-Rider Deluxe is a motorized, battery-operated, four-wheel scooter used for transportation by disabled persons.

The principles of operation of the proposed Opti-Rider Deluxe are identical to those of the predicate C.T.M. Mobility Scooter HS-686 scooter and other motorized vehicles legally marketed in the U.S. for use by disabled persons for transportation purposes. The Opti-Rider Deluxe, and other motorized four-wheeled vehicles, consists of a motorized chassis with a battery, drive unit, steering column, and electronics module. The user sits in a seat mounted on the chassis and operates the scooter via handpieces mounted on the steering column that also contains the console for control of the speed, emergency brake, and other features.

March 16, 2004

Hong-Seok Kim / President

Prescription Use ● AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033116

SK29

K033116

APR 1 2 2004

510(k) Summary
for
OPTI-RIDER DELUXE

1. SPONSOR

HANSUNG ECONET Co., Ltd.
#168, Wonnam-ri
Umbong-myon Asan
Chungnam 336-864
Korea

Contact Person: Hong-Seok Kim, President
Telephone: 82-41 541 5733

Date Prepared: September 29, 2003

2. DEVICE NAME

Proprietary Name: Opti-Rider Deluxe
Common/Usual Name: Scooter
Classification Name: Motorized three-wheeled vehicle

3. PREDICATE DEVICES

- C.T.M. Mobility Scooter HS-686 (K983662)
- Mega 4 Scooter (K982144)

4. DEVICE DESCRIPTION

The proposed Opti-Rider Deluxe consists of a motorized, four-wheeled chassis with batteries, drive unit, steering column, braking system, and electronics module for operational control of the vehicle. The user sits in a seat mounted on the chassis and operates the scooter via hand controls and a console mounted on the steering column.

5. INTENDED USE

The Opti-Rider Deluxe is a motorized, battery-operated, four-wheel scooter used for transportation by disabled persons.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed and predicate devices consist of a motorized chassis with four wheels, drive unit, steering column, and electronics module. The user sits in a seat mounted on the chassis and operates the scooter via hand controls mounted on the steering column. The steering column for the proposed and predicate devices also houses a console and controls for functions including speed, direction of travel, and features such as the horn, headlight, and directional signals. There are minor differences in the placement of these controls on the steering column, and the organization of the console, between the proposed and predicate devices.

The proposed Opti-Rider Deluxe and the predicate C.T.M. Mobility and Mega 4 Scooters have an electric braking system. The default status of the brakes is "on," and is disengaged only when the operator moves the throttle to place the scooter in motion.

Both the proposed and predicate devices are battery-operated and have on-board battery chargers. Performance characteristics such as maximum forward and reverse speed, turning radius, maximum safe incline, etc., are similar between the proposed and predicate devices.

7. PERFORMANCE TESTING

The Opti-Rider Deluxe was tested to demonstrate conformance with the requirements of FDA's "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles," issued July 6, 1995, and reformatted December 18, 1997. The Opti-Rider Deluxe is in compliance with the applicable requirements of ANSI/RESNA W/C Vol. 2 - 1998, Section 21.